REMARKS

This amendment is responsive to the Final Rejection dated October 20, 2004. Claim 1 has been amended herein. Claim 42 has been canceled. Claims 1-7, 9-20 and 38-41 will be pending in the present application upon entry of this amendment.

Claim 1 has been amended to provide the proper antecedent basis for claim 4 and to insert the subject matter of claim 42.

Entry of the amendments to claim 1 is requested either to: (1) place the application in condition for allowance, or (2) to place the application in better form for appeal. The amendments to claim 1 do not raise new issues since the applicant has merely inserted the subject matter of already present dependent claims 4 and 42 into claim 1.

Information Disclosure Statements

The applicant would like to thank the Examiner for initialing and returning a copy of form PTO-1449 from the Information Disclosure Statement that was filed on April 9, 2004. However, it appears that reference 25OD was overlooked in the initialing of the form PTO-1449. For 25OD, the name of the author, publication date and page were provided. Accordingly, the Examiner is requested to issue a new, initialed form PTO-1449 initialing reference 25OD.

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 4-6 have been rejected under 35 U.SC. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which the applicant regards as the invention.

In particular, the Examiner rejected claim 4, which depends from claim 1, for lacking proper antecedent basis for the particular antioxidants claimed in claim 4. Applicant has amended claim 1 to include the recitation of the particular antioxidants galangin, rutin, luteolin, morin, fisetin, silymarin, apigenin, gingkolides, hesperitin, cyanidin, citrin, and curcuminoid. It is considered that this amendment obviates the rejection. Accordingly, withdrawal of the rejection to claim 4 under 35 U.S.C. § 112, second paragraph is respectfully requested.

The Examiner has also rejected claims 5 and 6 for employing the term "comprising" as a transitional phrase. In particular, the Examiner bases this rejection on the statement that, "The transitional phrases [sic] 'consisting of' employed in the claim [claim 1] is closed-ended and

does exclude additional, unrecited elements or method steps." (See Final Rejection page 4, lines 9-10). This conclusion is incorrect for two reasons: (1) the transitional phrase of claim 1 is "comprises," and (2) the "consisting of" terminology referred to by the Examiner is part of the standard terminology for introducing a Markush group, i.e. "selected from the group consisting of" and thus this terminology is not a transitional phrase at all.

Specifically, the Examiner's attention is directed to line 3 of claim 1, which employs the transitional phrase, "comprises" as the transitional phrase for the composition referenced in claim 1. The transitional phrase "comprises" is found after the preamble and it precedes the Markush group terminology "selected from the group consisting of." Moreover, the terminology "selected from the group consisting of" is not a transitional phrase of the type cited by the Examiner, but rather introduces a Markush group. See MPEP § 2173.05(h). Applicant respectfully submits that the use of the term "comprises" in claims 5 and 6 is proper as claim 1 provides antecedent basis for its use. Accordingly, withdrawal of the rejections to claims 5 and 6 under 35 U.S.C. § 112, second paragraph is respectfully requested.

Double Patenting Rejections

The Examiner has provisionally rejected claims 1, 4-9 and 12-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of co-pending U.S. patent application no. 10/288,761. Because as the claims in the co-pending application have not yet issued and may be amended, Applicant hereby requests deferral of this rejection until such time as notice of allowance in said co-pending application is received. Applicant preserves its' right to traverse this rejection.

The Examiner has provisionally rejected claims 1, 4-9 and 12-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of co-pending U.S. patent application no. 10/279,315. Because as the claims in the co-pending application have not yet issued and may be amended, Applicant hereby requests deferral of this rejection until such time as notice of allowance in said co-pending application is received. Applicant preserves its' right to traverse this rejection.

Rejections under 35 U.S.C. § 103(a)

Claims 1-4, 7, 9-20, 38 and 42 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,162,801, issued to Kita (hereinafter "Kita"), Bissett, D.L. *et al.*, *J. Soc. Cosmet. Chem.* **1992**, *43*, 85-92 (hereinafter "Bissett"), and Darr, D. *et al.*, *British Journal of Dermatology* **1992**, *127*, 247-253 (hereinafter "Darr"), in view of Shimoi, K., *et al.*, *Mutation Research* **1996**, *350*, 153-161 (hereinafter "Shimoi") and U.S. Patent No. 5,776,460, issued to Kim et al. (hereinafter "Kim"). Applicant respectfully traverses this rejection for the reasons set forth below.

Applicant respectfully submits that the Official Action does not set forth a *prima facie* case of obviousness in support of the rejection under 35 U.S.C. § 103(a). According to M.P.E.P. § 2143,

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. [*Citation omitted.*]

The Examiner's rejection does not set forth a *prima facie* case of obviousness at least because the following two elements of claim 1, as amended, are completely lacking from the cited references:

(1) oral administration of D vitamins for the purpose of treating radiation injury, and

(2) the use of either D vitamins or the antioxidants of claim 1 to treat radiation injury resulting from proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

Kita teaches the topical application of D vitamins to prevent or treat UV-induced damage to the eyes or skin and states that the D vitamins function as a UV-screen. That is, according to Kita, an external layer of vitamin D will protect the eyes or the skin against UV-induced damage

by absorbing the UV radiation before it reaches the body. *See* Kita at col. 4, lines 40-44, and at col. 6, lines 17-20.

By contrast, Applicant's claimed invention is a method of treating or reducing radiation injury by **orally** administering a composition comprising one or more compounds effective to inhibit at least one of cell differentiation and cell proliferation, for example, a D vitamin, and one or more antioxidants. Kita does not teach or suggest that a D vitamin, administered **orally**, would provide any beneficial effect against UV-induced damage. Moreover, a skilled person reading Kita would not expect oral administration of a D vitamin to provide a beneficial effect against UV-damage because the invention of Kita relies on the D vitamin absorbing the UV radiation to prevent exposure of the skin to the harmful UV radiation. *See* Kita at col. 4, lines 40-44, and at col. 6, lines 17-20.

For the methodology of Kita to work, the D-vitamin must be physically located between the source of the UV radiation (the sun) and the skin in order to absorb the radiation. In the case of oral ingestion of the D vitamin, the D vitamin is not physically located between the sun and the skin and thus would not be in a position to absorb UV radiation. Moreover, the Examiner has presented no evidence that orally administered vitamin D would be present on the surface of the skin so that it can absorb UV radiation in accordance with the teachings of Kita. Thus, the skilled person would immediately and unequivocally conclude that oral administration of a D vitamin would likely be ineffective for the purpose of Kita, since the D vitamin would not be interposed between the UV radiation and the skin and thus would not be positioned to absorb UV radiation as taught by Kita. *See* Kita at col. 4, lines 40-44, and at col. 6, lines 17-20.

Moreover, a skilled person in the pharmaceutical arts would not conclude that oral administration of a composition would be effective based on evidence that topical administration is effective for a similar purpose. It this were the case, people would be eating sunscreen to prevent sunburn and rubbing aspirin on their skin to treat headaches with the expectation that these treatments would work. Skilled persons, however, do not extrapolate oral utility from topical utility since it is well known that topical products act in a completely different manner than orally ingested products, and that topical products absorb into the body in a completely different manner than orally ingested products. Shimoi, cited by the Examiner, for example, was aware that flavonoids exhibited *in vitro* activity as antioxidants and yet, even then, Shimoi considered it necessary to conduct experiments to determine whether the same flavonoids would

exhibit antioxidant activity *in vivo*, thereby confirming that skilled persons do not even conclude from *in vitro* testing that the same activity will be present *in vivo*.

On page 11 of the Office Action, the Examiner points out that Kita, in summarizing the prior art, mentions that therapeutic vitamin D may be administered orally or by injection. See col. 1, lines 42-44 of Kita. From this, the Examiner concludes that Kita teaches oral administration of D vitamins for the purpose of treating injury from UV radiation. However, this conclusion is incorrect because the prior art oral administration mentioned by Kita and relied on by the Examiner is not for the purpose of treating radiation injury, but rather, is for the purpose of treating one or more conditions selected from, "...rickets, osteomalacia, osteoporosis, osteatis, fibrosa, osteosclerosis and other bone diseases, and malignant tumors such as breast and colon cancers..." See col. 1, lines 16-21 of Kita. This provides the skilled person with no teaching or suggestion that oral administration of vitamin D would have any beneficial effect in the treatment of radiation injury.

Another problem with the Examiner's position is the title of Kita, which reads, "**External** Opthalmic Preparation Containing Vitamin D." From this, it is clear that Kita does not teach or suggest the internal administration of Vitamin D, as in the present invention.

On pages 11-12 of the Office Action, the Examiner also takes the position that because Kita teaches that, "In general, the ultraviolet (UV) light absorption spectra of vitamin D and active vitamin D have absorption maxima at 265 nm, with the molar absorption coefficients of about 18900," one of skill in the art would have found it obvious to administer a vitamin D orally in treating radiation injury in a human. The applicant disagrees since if the vitamin D is administered orally, it will be internal to the body. As a result, the vitamin D will not be located between the body or skin and the UV radiation. As a result, the vitamin D will not be in the path of the UV radiation and therefore would not be able to absorb it. Also, the Examiner has not made a showing that the orally administered vitamin D would be present on the skin in order to absorb UV radiation.

Skilled persons are aware that the process of absorption requires contact between the absorbent and the UV radiation in order to occur. In the case of oral administration of vitamin D, there is no evidence in the record that there would be any contact between the absorbent, vitamin D, and the UV radiation, and thus the vitamin D would not be expected absorb the UV radiation

if administered orally, as is required for it to perform its absorbent function according to Kita. *See* Kita at col. 4, lines 40-44, and at col. 6, lines 17-20.

Another reason that the rejection should be withdrawn is that, as noted in the Official Action, Kita, Bissett, Darr, and Shimoi set forth compositions and methods related to exposure to ultraviolet radiation. Claim 1 has been amended to insert the limitation of claim 42 therein. Claim 1 now requires that the radiation be selected from proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation. The types of radiation specifically recited in amended claim 1 do not appear to be mentioned in the cited references. Thus, the cited references lack another element of claim 1, namely, a disclosure of the type of radiation claimed. Accordingly, the cited references also do not make out a *prima facie* case of obviousness for the additional reason that this additional claim element is completely lacking from the references.

Moreover, applicant respectfully submits that there can be no reasonable expectation that treatments known to be effective against UV radiation would, in combination, be successful as a treatment for radiation injury caused by the types of radiation specified in claim 1, since these types of radiation have different wavelengths than UV radiation and are well-known to cause far more severe injuries than UV radiation. The different wavelengths are important because there is no evidence in the record suggesting that D vitamins absorb radiation of the type now required by claim 1. Note that Kita only mentions that D vitamins absorb at wavelengths in the neighborhood of 260 nm. The types of radiation specified in claim 1 have shorter wavelengths than UV radiation and thus, from the teachings of Kita, a skilled person would not expect them to be absorbed by D vitamins.

Moreover, the claimed types of radiation also have a higher energy than UV radiation since energy is known to be inversely proportional to the wavelength of the radiation. This higher energy results in far more severe injuries than are caused by UV radiation.

More specifically, radiation dermatitis is considered to be a serious, irreversible injury, which results primarily from exposure of the skin to high-energy **ionizing radiation** such as the types of radiation now specified in claim 1. See the publication "What is Ionizing Radiation" (6 pages) taken from http://tis.eh.doe.gov/ohre/roadmap/achre/into_9_1.html, enclosed herewith. Ionizing radiation is defined therein as any form of radiation that has enough energy to knock electrons out of atoms or molecules, creating ions. See page 2 of "What is Ionizing Radiation" and pages 1-2 of "Ionization Radiation" taken from

http://www.che.ilstu.edu/genchemhelphomepage/topicreview/bp/ch23/radiation.html, enclosed herewith, and, "Ionizing and Non-Ionizing Radiation" taken from http://www.epa.gov/radiation/understand/ionize_nonionize.htm, also enclosed herewith. Non-ionizing radiation is characterized by extremely low frequency with extremely long wavelengths. Non-ionizing radiation does not carry sufficient energy to excite the motion of atoms or molecules to induce the movement, i.e. the "excitation" of an electron from an occupied orbital to an empty, higher-energy orbital. The dividing line between ionizing and non-ionizing radiation is around 1216 kJ/mole, the energy required to excite a water molecule.

Ionizing radiation is thus distinguishable from, for example, actinic radiation, i.e. ultraviolet or violet radiation since ionizing radiation has significantly more energy than ultraviolet radiation. In fact it would take about 1.5 million joules of non-ionizing radiation to kill the average human being. In contrast, it takes only about 300 joules of x-ray or gamma radiation to cause fatal effects in humans. Alpha radiation exposure requires only about 15 joules to kill. (See "Ionizing & Non-Ionizing Radiation" cited above) As a result, the types of damage to the skin caused by ionizing radiation, is of a different kind and severity than is typically caused by exposure of the skin to relatively lower energy actinic radiation such as ultraviolet radiation.

The Examiner will note that UV radiation is not listed as a form of ionizing radiation in the publication, "Ionizing Radiation" cited above.

In "Understanding Radiation" available at http://www.epa.gov/radiation/understand/health_effects.htm, the health effects of exposure to various levels of ionizing radiation are outlined. (See page 3). As can be seen from the chart exposure to a low a dose of even a few rem of ionizing radiation results in severe radiation burns. Exposure to as few as 5-10 rems results in blood chemistry changes within hours of the exposure.

In contrast, the article "Sunburn" by James Foster, MD, MS, of the Alverado Hospital Medical Center (12 pages) found at http://www.emedicine.com/EMERG/topic798.htm points out on page 1 of 12 that the most common deleterious effect of exposure to ultraviolet radiation is sunburn or solar erythema. This article also points out that long-term sun exposure may lead to the development of cancers such as basal cell carcinoma, squamous cell carcinoma and

malignant melanoma. See page 2 of 12 of "Sunburn." These are the types of injury caused by exposure to the relatively lower energy ultraviolet or actinic radiation.

The article "Sunburn" by James Foster, MD, MS points out on page 5 that UV radiation that reaches the earth has wavelengths of 290-400 nm and that UV radiation having wavelengths of 200-290 nm is filtered out or absorbed in the outer atmosphere and is not encountered at sea level. In view of this fact, the skilled person would be led to conclude that the topical application of D vitamins, as taught by Kita, would likely be ineffective to absorb UV radiation as Kita suggests since Kita teaches that D vitamins absorb wavelengths of about 260 nm, wavelengths that do not pass through the outer atmosphere and thus that are not encountered at sea level.

The article, "Radiation Safety Answers, Answer to Question #13," by Aggie Barlow, Radiation Safety Officer, Yale University (4 pages) found at http://www.yale.edu/oehs/rdsfq13.htm discusses the harmful effects of one type of higher energy ionizing radiation, namely, x-ray radiation. X-ray radiation has approximately 1000 times the energy of ultraviolet radiation since the wavelength of x-ray radiation is approximately 1000 times shorter than the wavelength of ultraviolet radiation and the energy of radiation is inversely proportional to the wavelength of the radiation.

Accordingly, from the above publications, it can be concluded that radiation dermatitis is a known illness, which is considered irreversible, and which is different than the damage that is caused by exposure to ultraviolet radiation. It can also be concluded that the mechanism causing radiation dermatitis is most likely associated with the knocking out of electrons from, for example, skin cells or elements thereof due to exposure to high-energy ionizing radiation, which phenomena does not typically occur as a result of exposure to the significantly lower energy ultraviolet radiation. This demonstrates that the types of radiation now specified in claim 1 are significant because they cause a different kind of injury in a different way, than injuries typically caused by ultraviolet radiation and not just a different degree of injury as the Examiner suggests.

Therefore, it is considered that the present claims, which are specifically drawn to the treatment of radiation injury caused by ionizing radiation, clearly distinguish the present invention from all of the prior art relied upon by the Examiner.

The remaining references cited in the Final Rejection, that is, Bissett, Darr, Shimoi, and Kim, include descriptions of the use of various antioxidants, or other materials to treat UV

radiation-induced damage. However, none of these references cures the deficiencies of the primary reference to Kita since none of these references discloses:

(1) administration of D vitamins for the purpose of treating radiation injury, or

(2) use of either D vitamins or the antioxidants of claim 1 to treat radiation injury resulting from proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

Applicant submits that the cited references do not contain every element of a *prima facie* case of obviousness, since at least these two elements of claim 1 are missing from the cited references and All of the dependent claims currently pending in the present application ultimately depend from independent claim 1. Accordingly, Applicant submits that the Official Action does not set forth a *prima facie* case for the obviousness of any pending claim of the present application over the cited references.

In addition, the cited references provide no teaching or suggestion that would provide a skilled person with an expectation of successfully treating radiation injury from one of the types of radiation claimed in claim 1, by oral administration of a composition including vitamin D. Therefore, for this additional reason, the cited references do not set forth a case of *prima facie* obviousness.

Thus, the Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn upon reconsideration.

Claims 5-6 and 39-41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kita, and Bissett, and Darr, in view of Shimoi and Kim, further in view of Ishida et al. (U.S. 5,141,741, herein after "Ishida") or Nguyen et al (U.S. 5,650,137, hereinafter "Nguyen"). In particular, the Examiner cites Ishida for disclosing alpha lipoic acid and vitamins for use in lotions to prevent sunburns. Nguyen is cited for disclosing superoxide dismutase and chlorophyllin for the protection of skin against UV radiation (i.e. sunburns).

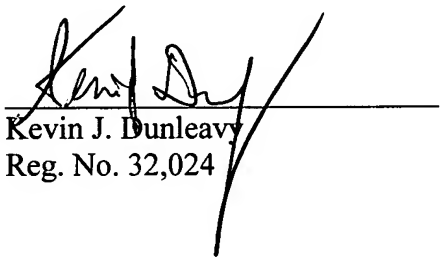
Applicant respectfully traverses this rejection for at least the following reasons. Claims 5-6 and 39-41 all depend from claim 1. Thus, claims 5-6 and 39-41 are considered to be patentable for at least the same reasons given above with respect to the patentability of claim 1.

Neither Ishida nor Nguyen cures the deficiencies of the remaining references. Ishida discloses a lotion for the topical application to skin to prevent UV light induced skin damage, mainly sunburns, while Nguyen teaches the use of superoxide dismutase and chlorophyllin for the protection against UV light damage. Nowhere in any of the cited references is there any teaching to use these components for treatment of radiation injury from any of the types of radiation now specified in claim 1. Moreover, neither of Ishida or Nguyen teaches oral administration of a composition for treatment or prevention of radiation injury.

Therefore, Applicant respectfully requests that the rejection over Kita, and Bissett, and Darr, in view of Shimoi and Kim, further in view of Ishida or Nguyen be withdrawn upon reconsideration.

In view of the foregoing amendments and remarks, Applicant respectfully submits that all of the pending claims are in condition for allowance and respectfully requests a favorable Office Action so indicating.

Respectfully submitted,



Dated: January 21, 2005

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What Is Ionizing Radiation?

What is *radiation*?

Radiation is a very general term, used to describe any process that transmits energy through space or a material away from a source. Light, sound, and radio waves are all examples of radiation. When most people think of radiation, however, they are thinking of *ionizing radiation*--radiation that can disrupt the atoms and molecules within the body. While scientists think of these emissions in highly mathematical terms, they can be visualized either as subatomic particles or as rays. Radiation's effects on humans can best be understood by first examining the effect of radiation on *atoms*, the basic building blocks of matter.

What is *ionization*?

Atoms consist of comparatively large particles (protons and neutrons) sitting in a central nucleus, orbited by smaller particles (electrons): a miniature solar system. Normally, the number of protons in the center of the atom equals the number of electrons in

orbit. An *ion* is any atom or molecule that does not have the normal number of electrons. *Ionizing radiation* is any form of radiation that has enough energy to knock electrons out of atoms or molecules, creating ions.

How is ionizing radiation measured?

Measurement lies at the heart of modern science, but a number by itself conveys no information. Useful measurement requires both an instrument for measurement (such as a stick to mark off length) and an agreement on the *units* to be used (such as inches, meters, or miles). The units chosen will vary with the *purpose* of the measurement. For example, a cook will measure butter in terms of tablespoons to ensure the meal tastes good, while a nutritionist may be more concerned with measuring calories, to determine the effect on the diner's health.

The variety of units used to measure radiation and radioactivity at times confuses even scientists, if they do not use them every day. It may be helpful to keep in mind the *purpose* of various units. There are two basic reasons to measure radiation: the study of physics and the study of the biological effects of radiation. What creates the complexity is that our instruments measure *physical* effects, while what is of interest to some are *biological* effects. A further complication is that units, as

What Is Ionizing Radiation?

What Is Radioactivity?

What Are Atomic Number and Atomic Weight?

Radioisotopes: What Are They and How Are They Made?

How Does Radiation Affect Humans?

How Do We Measure the Biological Effects of External Radiation?

How Do We Measure the Biological Effects of Internal Emitters?

with words in any language, may fade from use and be replaced by new units.

Radiation is not a series of distinct events, like radioactive decays, which can be counted individually. Measuring radiation in bulk is like measuring the movement of sand in an hourglass; it is more useful to think of it as a continuous flow, rather than a series of separate events. The *intensity* of a beam of ionizing radiation is measured by counting up how many ions (how much electrical charge) it creates in air. The *roentgen* (named after Wilhelm Roentgen, the discoverer of x rays) is the unit that measures the ability of x rays to ionize air; it is a unit of exposure that can be measured directly. Shortly after World War II, a common unit of measurement was the *roentgen equivalent physical (rep)*, which denoted an ability of other forms of radiation to create as many ions in air as a roentgen of x rays. It is no longer used, but appears in many of the documents examined by the Advisory Committee.

What are the basic types of ionizing radiation?

There are many types of ionizing radiation, but the most familiar are *alpha*, *beta*, and *gamma/x-ray* radiation. *Neutrons*, when expelled from atomic nuclei and traveling as a form of radiation, can also be a significant health concern.

How Do Scientists Determine the Long-Term Risks from Radiation?

Alpha particles are clusters of two neutrons and two protons each. They are identical to the nuclei of atoms of helium, the second lightest and second most common element in the universe, after hydrogen. Compared with other forms of radiation, though, these are very heavy particles--about 7,300 times the mass of an electron. As they travel along, these large and heavy particles frequently interact with the electrons of atoms, rapidly losing their energy. They cannot even penetrate a piece of paper or the layer of dead cells at the surface of our skin. But if released within the body from a radioactive atom inside or near a cell, alpha particles can do great damage as they ionize atoms, disrupting living cells. Radium and plutonium are two examples of alpha emitters.

Beta particles are electrons traveling at very high energies. If alpha particles can be thought of as large and slow bowling balls, beta particles can be visualized as golf balls on the driving range. They travel farther than alpha particles and, depending on their energy, may do as much damage. For example, beta particles in fallout can cause severe burns to the skin, known as beta burns. Radiosotopes that emit beta particles are present in fission products produced in nuclear reactors and nuclear explosions. Some beta-emitting radioisotopes, such as iodine 131, are administered internally to patients to diagnose and treat disease.

Gamma and *x-ray* radiation consists of packets of energy known as *photons*. Photons have no mass or charge, and they travel in straight lines. The visible light seen by our eyes is also

made up of photons, but at lower energies. The energy of a gamma ray is typically greater than 100 kiloelectron volts (keV--"k" is the abbreviation for *kilo*, a prefix that multiplies a basic unit by 1,000) per photon, more than 200,000 times the energy of visible light (0.5 eV). If alpha particles are visualized as bowling balls and beta particles as golf balls, photons of gamma and x-radiation are like weightless bullets moving at the speed of light. Photons are classified according to their origin. Gamma rays originate from events within an atomic nucleus; their energy and rate of production depend on the radioactive decay process of the radionuclide that is their source. X rays are photons that usually originate from energy transitions of the electrons of an atom. These can be artificially generated by bombarding appropriate atoms with high-energy electrons, as in the classic x-ray tube. Because x rays are produced artificially by a stream of electrons, their rate of output and energy can be controlled by adjusting the energy and amount of the electrons themselves. Both x rays and gamma rays can penetrate deeply into the human body. How deeply they penetrate depends on their energy; higher energy results in deeper penetration into the body. A 1 MeV ("M" is the abbreviation for *mega*, a prefix that multiplies a basic unit by 1,000,000) gamma ray, with an energy 2,000,000 times that of visible light, can pass completely through the body, creating tens of thousands of ions as it does.

A final form of radiation of concern is *neutron* radiation. Neutrons, along with protons, are one of the components of the atomic nucleus.

Like protons, they have a large mass; unlike protons, they have no electric charge, allowing them to slip more easily between atoms. Like a Stealth fighter, high-energy neutrons can travel farther into the body, past the protective outer layer of the skin, before delivering their energy and causing ionization.

Several other types of high-energy particles are also ionizing radiation. Cosmic radiation that penetrates the Earth's atmosphere from space consists mainly of protons, alpha particles, and heavier atomic nuclei. Positrons, mesons, pions, and other exotic particles can also be ionizing radiation.

Ionizing Radiation

Ionizing Versus Non-Ionizing Radiation	Biological Effects of Ionizing Radiation

Ionizing Versus Non-Ionizing Radiation

We live in a sea of radiation. In recent years, people have learned to fear the effects of radiation. They don't want to live near nuclear reactors. They are frightened by reports of links between excess exposure to sunlight and skin cancer. They are afraid of the leakage from microwave ovens, or the radiation produced by their television sets.

Several factors combine to heighten the public's anxiety about both the short-range and long-range effects of radiation. Perhaps the most important source of fear is the fact that radiation can't be detected by the average person. Furthermore, the effects of exposure to radiation might not appear for months or years or even decades.

To understand the biological effects of radiation we must first understand the difference between **ionizing radiation** and **non-ionizing radiation**. In general, two things can happen when radiation is absorbed by matter: excitation or ionization.

- *Excitation* occurs when the radiation excites the motion of the atoms or molecules, or excites an electron from an occupied orbital into an empty, higher-energy orbital.
- *Ionization* occurs when the radiation carries enough energy to remove an electron from an atom or molecule.

Because living tissue is 70-90% water by weight, the dividing line between radiation that excites electrons and radiation that forms ions is often assumed to be equal to the ionization of water: 1216 kJ/mol. Radiation that carries less energy can only excite the water molecule. It is therefore called *non-ionizing radiation*. Radiation that carries more energy than 1216 kJ/mol can remove an electron from a water molecule, and is therefore called *ionizing radiation*.

The table below contains estimates of the energies of various kinds of radiation. Radio waves, microwaves, infrared radiation, and visible light are all forms of non-ionizing radiation. X-rays, γ-rays, and α- and β-particles are forms of ionizing radiation. The dividing line between ionizing and non-ionizing radiation in the electromagnetic spectrum falls in the ultraviolet portion of the spectrum. It is therefore useful to divide the UV spectrum into two categories: UV_A and UV_B. Radiation at the high-energy end of the UV spectrum can be as dangerous as x-rays or γ-rays.

Energies of Ionizing and Non-Ionizing Forms of Radiation

Radiation	*Typical Frequency (s^{-1})*	*Typical Energy (kJ/mol)*
Particles		
α-particles		4.1×10^8

β-particles		1.5×10^7	*ionizing radiation*
Electromagnetic radiation			
cosmic rays	$6 \times 10^{21} s^{-1}$	2.4×10^9	
γ-rays	$3 \times 10^{20} s^{-1}$	1.2×10^8	
x-rays	$3 \times 10^{17} s^{-1}$	1.2×10^5	
ultraviolet	$3 \times 10^{15} s^{-1}$	1200	*non-ionizing radiation*
visible	$5 \times 10^{14} s^{-1}$	200	
infrared	$3 \times 10^{13} s^{-1}$	12	
microwaves	$3 \times 10^9 s^{-1}$	1.2×10^{-3}	
radio waves	$3 \times 10^7 s^{-1}$	1.2×10^{-5}	

When ionizing radiation passes through living tissue, electrons are removed from neutral water molecules to produce H_2O^+ ions. Between three and four water molecules are ionized for every 1.6×10^{-17} joules of energy absorbed in the form of ionizing radiation.

$$H_2O \rightarrow H_2O^+ + e^-$$

The H_2O^+ ion should not be confused with the H_3O^+ ion produced when acids dissolve in water. The H_2O^+ ion is an example of a *free radical*, which contains an unpaired valence-shell electron. Free radicals are extremely reactive. The radicals formed when ionizing radiation passes through water are among the strongest oxidizing agents that can exist in aqueous solution. At the molecular level, these oxidizing agents destroy biologically active molecules by either removing electrons or removing hydrogen atoms. This often leads to damage to the membrane, nucleus, chromosomes, or mitochondria of the cell that either inhibits cell division, results in cell death, or produces a malignant cell.

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Biological Effects of Ionizing Radiation

From the time that radioactivity was discovered, it was obvious that it caused damage. As early as 1901, Pierre Curie discovered that a sample of radium placed on his skin produced wounds that were very slow to heal. What some find surprising is the magnitude of the difference between the biological effects

of non-ionizing radiation, such as light and microwaves, and ionizing radiation, such as high-energy ultraviolet radiation, x-rays, γ-rays, and α- or β-particles.

Radiation at the low-energy end of the electromagnetic spectrum, such as radio waves and microwaves, excites the movement of atoms and molecules, which is equivalent to heating the sample. Radiation in or near the visible portion of the spectrum excites electrons into higher-energy orbitals. When the electron eventually falls back to a lower-energy state, the excess energy is given off to neighboring molecules in the form of heat. The principal effect of non-ionizing radiation is therefore an increase in the temperature of the system.

We experience the fact that biological systems are sensitive to heat each time we cook with a microwave oven, or spend too long in the sun. But it takes a great deal of non-ionizing radiation to reach dangerous levels. We can assume, for example, that absorption of enough radiation to produce an increase of about 6°C in body temperature would be fatal. Since the average 70-kilogram human is 80% water by weight, we can use the heat capacity of water to calculate that it would take about 1.5 million joules of non-ionizing radiation to kill the average human. If this energy was carried by visible light with a frequency of 5×10^{14} s^{-1}, it would correspond to absorption of about seven moles of photons.

Ionizing radiation is much more dangerous. A dose of only 300 joules of x-ray or γ-ray radiation is fatal for the average human, even though this radiation raises the temperature of the body by only 0.001°C. α-particle radiation is even more dangerous; a dose equivalent to only 15 joules is fatal for the average human. Whereas it takes seven moles of photons of visible light to produce a fatal dose of non-ionizing radiation, absorption of only 7×10^{-10} moles of the α-particles emitted by ^{238}U is fatal.

There are three ways of measuring ionizing radiation.

- Measure the *activity* of the source in units of disintegrations per second or curies, which is the easiest measurement to make.
- Measure the radiation to which an object is *exposed* in units of roentgens by measuring the amount of ionization produced when this radiation passes through a sample of air.
- Measure the radiation *absorbed* by the object in units of radiation absorbed doses or "rads." This is the most useful quantity, but it is the hardest to obtain.

One **radiation absorbed dose**, or **rad**, corresponds to the absorption of 10^{-5} joules of energy per gram of body weight. Because this is equivalent to 0.01 J/kg, one rad produces an increase in body temperature of about 2×10^{-6}°C. At first glance, the rad may seem to be a negligibly small unit of measurement. The destructive power of the radicals produced when water is ionized is so large, however, that cells are inactivated at a dose of 100 rads, and a dose of 400 to 450 rads is fatal for the average human.

Not all forms of radiation have the same efficiency for damaging biological organisms. The faster energy is lost as the radiation passes through the tissue, the more damage it does. To correct for the differences in **radiation biological effectiveness** (**RBE**) among various forms of radiation, a second unit of absorbed dose has been defined. The **roentgen equivalent man,** or **rem**, is the absorbed dose in rads times the biological effectiveness of the radiation.

rems = rads x RBE

Values for the RBE of different forms of radiation are given in the table below.

The Radiation Biological Effectiveness of Various Forms of Radiation

Radiation	*RBE*
x-rays and ɣ-rays	1
ß⁻ particles with energies larger than 0.03 MeV	1
ß⁻ particles with energies less than 0.3 MeV	1.7
thermal (slow-moving) neutrons	3
fast-moving neutrons or protons	10
α-particles or heavy ions	20

Estimates of the per capita exposure to radiation in the United States are summarized in the table below. These estimates include both external and internal sources of natural background radiation.

Average Whole-Body Exposure Levels for Sources of Ionizing Radiation

Source	*Per Capita Dose (rems / y)*
natural background	0.082
medical x-rays	0.077
nuclear test fallout	0.005
consumer and industrial products	0.005
nuclear power industry	0.001
total:	0.170

External sources include cosmic rays from the sun and α-particles or ɣ-rays emitted from rocks and soil. Internal sources include nuclides that enter the body when we breathe (^{14}C, ^{85}Kr, ^{220}Rn, and ^{222}Rn) and through the food chain (^{3}H, ^{14}C, ^{40}K, ^{90}Sr, ^{131}I, and ^{137}Cs). The actual dose from natural radiation depends on where one lives. People who live in the Rocky Mountains, for example, receive twice as much background radiation as the national average because there is less atmosphere to filter out the cosmic rays from the sun. The average dose from medical x-rays has decreased in recent years because of advances in the sensitivity of the photographic film used for x-rays. Radiation from nuclear test fallout has also decreased as a result of the atmospheric nuclear test ban. The threat of fallout from the testing of nuclear weapons can be appreciated by noting that a Chinese atmospheric test in 1976 led to the contamination of milk in the Harrisburg, PA, vicinity at a level of 300 pCi (3.00×10^{-10} Ci) per lite. This was about eight times the level of contamination (41 pCi per liter) that resulted from the accident at Three Mile Island.

The contribution to the radiation absorbed dose from consumer and industrial products includes radiation from construction materials, x-rays emitted by television sets, and inhaled tobacco smoke. The most recent estimate of the total radiation emitted from the mining and milling of uranium, the fabrication of reactor fuels, the storage of radioactive wastes, and the operation of nuclear reactors is less than 0.001 rem per year.

The total dose from ionizing radiation for the average American is about 0.170 rem per year. The Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences recently estimated that an increase in this dose to a level of 1 rem per year would result in 169 additional deaths from cancer per million people exposed. This can be compared with the 170,000 cancer deaths that would normally occur in a population this size that was not exposed to this level of radiation.

The principal effect of low doses of ionizing radiation is to induce cancers, which may take up to 20 years to develop. What is the effect of high doses of ionizing radiation? Cells that are actively dividing are more sensitive to radiation than cells that aren't. Thus, cells in the liver, kidney, muscle, brain, and bone are more resistant to radiation than the cells of bone marrow, the reproductive organs, the epithelium of the intestine, and the skin, which suffer the most damage from radiation. Damage to the bone marrow is the main cause of death at moderately high levels of exposure (200 to 1000 rads). Damage to the gastrointestinal tract is the major cause of death for exposures on the order of 100 to 10,000 rads. Massive damage to the central nervous system is the cause of death from extremely high exposures (over 10,000 rads).

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U.S. Environmental Protection Agency

Understanding Radiation

Ionizing & Non-Ionizing Radiation

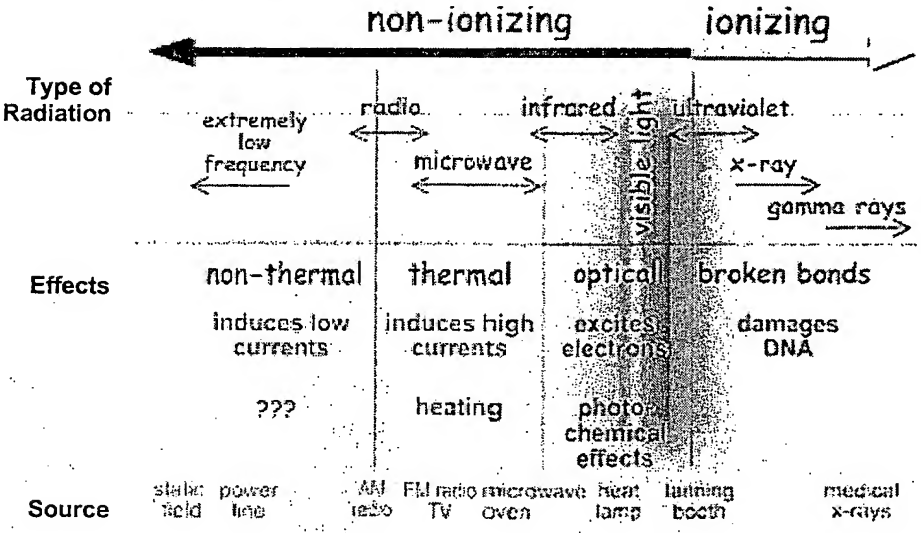
Radiation having a wide range of energies form the electromagnetic spectrum, which is illustrated below. The spectrum has two major divisions: non-ionizing and ionizing radiation.

Radiation that has enough energy to move atoms in a molecule around or cause them to vibrate, but not enough to remove electrons, is referred to as "non-ionizing radiation." Examples of this kind of radiation are sound waves, visible light, and microwaves.

Radiation that falls within the ionizing radiation" range has enough energy to remove tightly bound electrons from atoms, thus creating ions. This is the type of radiation that people usually think of as 'radiation.' We take advantage of its properties to generate electric power, to kill cancer cells, and in many manufacturing processes.

The energy of the radiation shown on the spectrum below increases from left to right as the frequency rises.

Types of Radiation in the Electromagnetic Spectrum



Nonionizing Radiation

We take advantage of the properties of non-ionizing radiation for

common tasks:

- microwave radiation-- telecommunications and heating food
- infrared radiation --infrared lamps to keep food warm in restaurants
- radio waves-- broadcasting

Non-ionizing radiation ranges from extremely low frequency radiation, shown on the far left through the audible, microwave, and visible portions of the spectrum into the ultraviolet range.

Extremely low-frequency radiation has very long wave lengths (on the order of a million meters or more) and frequencies in the range of 100 Hertz or cycles per second or less. Radio frequencies have wave lengths of between 1 and 100 meters and frequencies in the range of 1 million to 100 million Hertz. Microwaves that we use to heat food have wavelengths that are about 1 hundredth of a meter long and have frequencies of about 2.5 billion Hertz.

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Ionizing Radiation

Higher frequency ultraviolet radiation begins to have enough energy to break chemical bonds. X-ray and gamma ray radiation, which are at the upper end of magnetic radiation have very high frequency --in the range of 100 billion billion Hertz-- and very short wavelengths--1 million millionth of a meter. Radiation in this range has extremely high energy. It has enough energy to strip off electrons or, in the case of very high-energy radiation, break up the nucleus of atoms.

Ionization is the process in which a charged portion of a molecule (usually an electron) is given enough energy to break away from the atom. This process results in the formation of two charged particles or ions: the molecule with a net positive charge, and the free electron with a negative charge.

Each ionization releases approximately 33 electron volts (eV) of energy. Material surrounding the atom absorbs the energy. Compared to other types of radiation that may be absorbed, ionizing radiation deposits a large amount of energy into a small area. In fact, the 33 eV from one ionization is more than enough energy to disrupt the chemical bond between two carbon atoms. All ionizing radiation is capable, directly or indirectly, of removing electrons from most molecules.

There are three main kinds of ionizing radiation:

- alpha particles, which include two protons and two neutrons;
- beta particles, which are essentially electrons; and
- gamma rays and x-rays, which are pure energy (photons).

Nuclides & Isotopes

Health Effects

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Links to Related Information

Gamma Rays • Alpha Particles • Beta Particles • Why Are Some Atoms •

...protecting people and the environment

Last updated on Tuesday, November 30th, 2004
URL: http://www.epa.gov/radiation/understand/ionize_nonionize.htm

Health Effects

You can find answers to many common questions about the health effects of radiation in the following categories:

- radiation and health
- effects of radiation type and exposure pathway
- non-radiation health effects of radioactive materials
- estimating health effects

Radiation and Health

How does radiation cause health effects?

Radioactive materials that decay spontaneously produce ionizing radiation, which has sufficient energy to strip away electrons from atoms (creating two charged ions) or to break some chemical bonds. Any living tissue in the human body can be damaged by ionizing radiation. The body attempts to repair the damage, but sometimes the damage is too severe or widespread, or mistakes are made in the natural repair process. The most common forms of ionizing radiation are alpha and beta particles, or gamma and X-rays.

What kinds of health effects occur from exposure to radionuclides?

In general, the amount and duration of radiation exposure affects the severity or type of health effect. There are two broad categories of health effects: stochastic and non-stochastic.

Stochastic Health Effects

Stochastic effects are associated with long-term, low-level (chronic) exposure to radiation. ("Stochastic" refers to the likelihood that something will happen.) Increased levels of exposure make these health effects more likely to occur, but do not influence the type or severity of the effect.

Cancer is considered by most people the primary health effect from radiation exposure. Simply put, cancer is the uncontrolled growth of cells. Ordinarily, natural processes control the rate at which cells grow and replace themselves. They also control the body's processes for repairing or replacing damaged tissue. Damage occurring at the cellular or molecular level, can disrupt the control processes, permitting the uncontrolled growth of cells--cancer. This is why ionizing radiation's ability to break chemical bonds in atoms and molecules makes it such a potent carcinogen.

Other stochastic effects also occur. Radiation can cause changes in DNA, the "blueprints" that ensure cell repair and replacement produces a perfect copy of the original cell. Changes in DNA are called mutations.

Sometimes the body fails to repair these mutations or even creates mutations during repair. The mutations can be teratogenic or genetic. Teratogenic mutations affect only the individual who was exposed. Genetic mutations are passed on to offspring.

Non-Stochastic Health Effects

Non-stochastic effects appear in cases of exposure to high levels of radiation, and become more severe as the exposure increases. Short-term, high-level exposure is referred to as 'acute' exposure.

Many non-cancerous health effects of radiation are non-stochastic. Unlike cancer, health effects from 'acute' exposure to radiation usually appear quickly. Acute health effects include burns and radiation sickness. Radiation sickness is also called 'radiation poisoning.' It can cause premature aging or even death. If the dose is fatal, death usually occurs within two months. The symptoms of radiation sickness include: nausea, weakness, hair loss, skin burns or diminished organ function.

Medical patients receiving radiation treatments often experience acute effects, because they are receiving relatively high "bursts" of radiation during treatment.

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Is any amount of radiation safe?

There is no firm basis for setting a "safe" level of exposure above background for stochastic

effects. Many sources emit radiation that is well below natural background levels. This makes it extremely difficult to isolate its stochastic effects.

Some scientists assert that low levels of radiation are beneficial to health (this idea is known as hormesis).

However, there do appear to be threshold exposures for the various non-stochastic effects. (Please note that the acute affects in the following table are cumulative. For example, a dose that produces damage to bone marrow will have produced changes in blood chemistry and be accompanied by nausea.)

Exposure (rem)	Health Effect	Time to Onset
	radiation burns; more severe as exposure increases.	
5-10	changes in blood chemistry	
50	nausea	hours
55	fatigue	
70	vomiting	
75	hair loss	2-3 weeks
90	diarrhea	
100	hemorrhage	
400	death from fatal doses	within 2 months
1,000	destruction of intestinal lining	
	internal bleeding	
	death	1-2 weeks
2,000	damage to central nervous system	
	loss of consciousness	minutes
	death	hours to days

info@ Estimating Risk

How do we know radiation causes cancer?

Basically, we have learned through observation. When people first began working with radioactive materials, scientists didn't understand radioactive decay, and reports of illness were scattered.

As the use of radioactive materials and reports of illness became more frequent, scientists began to notice patterns in the illnesses. People working with radioactive materials and x-rays developed particular types of uncommon medical conditions. For example, scientists recognized as early at 1910 that radiation caused skin cancer. Scientists began to keep track of the health effects, and soon set up careful scientific studies of groups of people who had been exposed.

Among the best known long-term studies are those of Japanese atomic bomb blast survivors, other populations exposed to nuclear testing fallout (for example, natives of the Marshall Islands), and uranium miners.

 Decay Chains: Uranium Miners

Aren't children more sensitive to radiation than adults?

Yes, because children are growing more rapidly, there are more cells dividing and a greater opportunity for radiation to disrupt the process. EPA's radiation protection standards take into account the differences in the sensitivity due to age and gender.

Fetuses are also highly sensitive to radiation. However, the period during which they may be exposed is short.

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Effects of Radiation Type and Exposure Pathway

Both the type of radiation to which the person is exposed and the pathway by which they are exposed influence health effects. Different types of radiation vary in their ability to damage different kinds of tissue.

Radiation and radiation emitters (radionuclides) can expose the whole body (direct exposure) or expose tissues inside the body when inhaled or ingested. All kinds of ionizing radiation can cause cancer and other health effects. The main difference in the ability of alpha and beta particles and gamma and x-rays to cause health effects is the amount of energy they have. Their

energy determines how far they can penetrate into tissue. It also determines how much energy they are able to transmit directly or indirectly to tissues and the resulting damage.

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Non-Radiation Health Effects of Radionuclides

Radioactive elements and compounds behave chemically exactly like their non-radioactive forms. For example, radioactive lead has the same chemical properties as non-radioactive lead. The public health protection question that EPA's scientists must answer is, "How do we best manage all the hazards a pollutant presents?"

Protecting Against Exposure

Do chemical properties of radionuclides contribute to radiation health effects?

The chemical properties of a radionuclide can determine where health effects occur. To function properly many organs require certain elements. They cannot distinguish between radioactive and non-radioactive forms of the element and accumulate one as quickly as the other.

- Radioactive iodine concentrates in the thyroid. The thyroid needs iodine to function normally, and cannot tell the difference between stable and radioactive isotopes. As a result, radioactive iodine contributes to thyroid cancer more than other types of cancer.
- Calcium, strontium-90, and radium-226 have similar chemical properties. The result is that strontium and radium in the body tend to collect in calcium rich areas, such as bones and teeth. They contribute to bone cancer. return to: [top] [previous location]

Estimating Health Effects

What is the cancer risk from radiation? How does it compare to the risk of cancer from other sources?

Each radionuclide represents a somewhat different health risk. However, health physicists currently estimate that overall, if each person in a group of 10,000 people exposed to 1 rem of ionizing radiation, in small doses over a life time, we would expect 5 or 6 more people to die of cancer than would otherwise.

In this group of 10,000 people, we can expect about 2,000 to die of cancer from all non-radiation causes. The accumulated exposure to 1 rem of radiation, would increase that number to about 2005 or 2006.

To give you an idea of the usual rate of exposure, most people receive about 3 tenths of a rem (300 mrem) every year from natural background sources of radiation (mostly radon).

What are the risks of other long-term health effects?

Other than cancer, the most prominent long-term health effects are teratogenic and genetic mutations.

- Teratogenic mutations result from the exposure of fetuses (unborn children) to radiation. They can include smaller head or brain size, poorly formed eyes, abnormally slow growth, and mental retardation. Studies indicate that fetuses are most sensitive between about eight to fifteen weeks after conception. They remain somewhat less sensitive between six and twenty-five weeks old.

  The relationship between dose and mental retardation is not known exactly. However, scientists estimate that if 1,000 fetuses that were between eight and fifteen weeks old were exposed to one rem, four fetuses would become mentally retarded. If the fetuses were between sixteen and twenty-five weeks old, it is estimated that one of them would be mentally retarded.

- Genetic effects are those that can be passed from parent to child. Health physicists estimate that about fifty severe hereditary effects will occur in a group of one million live-born children whose parents were both exposed to one rem. About one hundred twenty severe hereditary effects would occur in all descendants.

  In comparison, all other causes of genetic effects result in as many as 100,000 severe hereditary effects in one million live-born children. These genetic effects include those that occur spontaneously ("just happen") as well as those that have non-radioactive causes.

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Protecting Against Exposure

What limits does EPA set on exposure to radiation?

Health physicists generally agree on limiting a person's exposure beyond background radiation to about 100 mrem per year from all sources. Exceptions are occupational, medical or accidental exposures. (Medical X-rays generally deliver less than 10 mrem). EPA and other regulatory agencies generally limit exposures from specific source to the public to levels well under 100 mrem. This is far below the exposure levels that cause acute health effects.

How does EPA protect against radionuclides that are also toxic?

In most cases, the radiation hazard is much greater than the chemical (toxic) hazard. Radiation protection limits are lower than the chemical hazard protection limits would be. By issuing radiation protection regulations, EPA can protect people from both the radiation and the chemical hazard. However, deciding which hazard is greater is not always straightforward. Several factors can tip the balance:

- toxicity of the radionuclide
- strength of the ionizing radiation
- how quickly the radionuclide emits radiation (half-life)
- relative abundance of the radioactive and non-radioactive forms

For example:

- Uranium-238 radioactive and very toxic. Its half-life of 4.5 billion years means that only a few atoms emit radiation at a time. A sample containing enough atoms to pose a radiation hazard contains enough atoms to pose a chemical hazard. As a result, EPA regulates uranium-238 as both a chemical and a radiation hazard.

- Radioactive isotopes of lead are both radioactive and toxic. In spite of the severe effects of lead on the brain and the nervous system, the radiation hazard is greater. However, the radioactive forms of lead are so uncommon that paint or other lead containing products do not contain enough radioactive lead to present a radiation hazard. As a result, EPA regulates lead as a chemical hazard. return to: [top] [previous location]

Links to Related Information

Radiation Protection Basics | Estimating Risk | Exposure Pathways

...protecting people and the environment

Last updated on Tuesday, November 30th, 2004
URL: http://www.epa.gov/radiation/understand/health_effects.htm

Sunburn

Last Updated: October 27, 2004

Synonyms and related keywords: sun burn, erythema solare, ultraviolet radiation, UVR

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INTRODUCTION

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Background: Sunburn is an acute cutaneous inflammatory reaction that follows excessive exposure of the skin to ultraviolet radiation (UVR). Long-term adverse health effects of repeated exposure to UVR

Related Articles

Burns, Chemical

Burns, Thermal

Cellulitis

Dermatitis, Atopic

Dermatitis, Contact

Dermatitis, Exfoliative

Heat Exhaustion and Heatstroke

Systemic Lupus Erythematosus

are well described but are beyond the scope of this article.

Pathophysiology: Exposure to solar radiation has the beneficial effects of stimulating the cutaneous synthesis of vitamin D and providing radiant warmth. Unfortunately, when the skin is subjected to excessive radiation in the ultraviolet range (wavelength <400 nm), deleterious effects may occur. The most common is acute sunburn or solar erythema.

Solar erythema is associated with microscopic changes in the skin, detectable within 30 minutes of exposure to UVR. The most characteristic changes include formation of epidermal sunburn cells, damaged keratinocytes with hyaline cytoplasm, and pyknotic nuclei. Epidermal Langerhans cell and mast cell numbers may decrease, while the relative percentage of hypogranulated or degranulated cells may increase. Superficial blood vessels show endothelial swelling, perivenular edema, and a mixed perivascular infiltrate.

The precise biochemical pathways that lead to the sunburn reaction are not well understood but appear to involve multiple inflammatory mediators, including histamine, prostaglandins, and cytokines.

Less intense or shorter-duration exposure to UVR results in an increase in skin pigmentation, known as tanning, which provides some protection against further UVR-induced damage. The increased skin pigmentation occurs in 2 phases, (1) immediate pigment darkening, and (2) delayed tanning. Immediate pigment darkening occurs during exposure to UVR and results from alteration of existing melanin (oxidation, redistribution). It may fade rapidly or persist for several days. Delayed tanning results from increased synthesis of epidermal melanin and requires a longer period of time to become visible (24-72 h). With repeated exposure to UVR, the skin thickens, primarily due to epidermal hyperplasia with thickening of the stratum corneum.

Frequency:

- **In the US:** Incidence is highest in areas with the highest flux of solar radiation (ie, the southern United States).
- **Internationally:** Incidence is increased in regions that are closer to the equator, that are higher in altitude, and where individuals have lighter baseline skin pigmentation.

Mortality/Morbidity:

- Uncomplicated sunburn is associated with minimal short-term morbidity. Most cases resolve spontaneously with no significant sequelae.

Patient Education

Burns Center

Sunburn Overview

Sunburn Causes

Sunburn Symptoms

Sunburn Treatment

- In rare cases, sunburn may be so severe and diffuse that it results in second-degree burns, dehydration, secondary infection, shock, or even death.

- Morbidity and mortality associated with long-term sun exposure is related primarily to the development of cutaneous neoplasms, including basal cell carcinoma, squamous cell carcinoma, and malignant melanoma.

Race: Lighter-skinned individuals are affected more frequently and severely. Skin types may be divided into 6 categories, based on an individual's tendency to tan and/or burn (see Table 1).

Table 1. Skin Phototypes

Skin Phototype	Description	Typical Features	MED	Minimum SPF
I	Always burns, never tans	White skin, blue/hazel eyes, blond/red hair	15-30 mJ/cm^2	≥15
II	Always burns, tans minimally	Fair skin, blue eyes	25-40 mJ/cm^2	≥15
III	Burns minimally, tans slowly	Darker Caucasian skin	30-50 mJ/cm^2	10-15
IV	Burns minimally, tans well	Light brown skin, Mediterranean	40-60 mJ/cm^2	6-10
V	Rarely burns, tans profusely/darkly	Brown skin, Middle Eastern, Latin American	60-90 mJ/cm^2	4-6
VI	Never burns, always tans, deeply pigmented	Dark brown or black skin	90-150 mJ/cm^2	None

Age: Most people get the majority of their sun exposure when young, making sunburn more common in children and young adults. Some elderly individuals have a blunted sunburn response.

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History:

- Recent sun exposure or outdoor activity; outdoor occupations or hobbies
- Erythema develops after 2-6 hours and peaks at 12-24 hours.
- Pain
- Possible fever, chills, malaise, nausea, or vomiting in severe cases
- Blistering
- Erythema that resolves over 4-7 days, usually with skin scaling and peeling
- Assess for exposure to photosensitizing drugs.

Physical:

- Patients at highest risk typically have fair skin, blue eyes, and red or blond hair.
- Immediate or early erythema occurs during UVR exposure and fades within 30 minutes.
- The acute inflammatory response is greatest 20-24 hours after exposure.
    - Erythema
    - Warmth
    - Tenderness
    - Edema
    - Blistering (severe cases)
- Fever can present in severe cases.
- Most exposure is limited to sun-exposed areas of the body; however, significant transmission of UVR may occur through some clothing, resulting in sunburn on clothed skin.
- Delayed scaling and desquamation occurs 4-7 days after exposure.

Causes:

- The electromagnetic spectrum can be divided according to wavelength into ultraviolet (<400 nm), visible (400-760 nm), and infrared (>760 nm).
    - Sunburn is caused by excessive exposure of the skin to UVR.
    - The ultraviolet spectrum can be divided into ultraviolet A (UV-A), 320-400 nm; ultraviolet B (UV-B), 290-320 nm; and ultraviolet C (UV-C), 200-290 nm.
    - Solar UVR of wavelengths shorter than 290 nm is filtered out or absorbed in the outer atmosphere and is not encountered at sea level.
    - UV-B radiation is much more potent at inducing erythema than UV-A and is, therefore, the principal cause of sunburn (about 85%).
    - However, UV-A comprises the majority of UVR reaching the surface of the earth (about 90% at midday) and, therefore, accounts for a significant percentage of the immediate and long-term cutaneous effects of UVR.
- The minimal single dose of UVR (energy per unit area) required to produce erythema at an exposed site is known as the minimal erythema dose (MED). Moderate-to-severe sunburn occurs at 3-8 MEDs.
- Multiple factors influence UVR-induced erythema.
    - Wavelength: UV-B is more erythemogenic than UV-A. Multiple wavelengths may result in an additive effect.
    - Skin pigmentation: Compared with white-skinned individuals, moderately pigmented races require 3-5 times more UVR exposure to cause erythema; blacks require up to 30 times more. Facultative (induced) tanning increases MEDs by only 2-3 times.
    - Skin thickness
    - Hydration: UVR penetrates moist skin more effectively than dry skin.
    - Anatomic site: MEDs are greater on the limbs than on the face, neck, and trunk.
    - Environmental reflection: Radiation is 80% reflected by

snow and ice, compared to 20% by sand.

- Altitude: UVR increases 4% for every 300-m (1000-ft) increase in elevation.
- Latitude: Exposure is greater at lower latitudes.
- Time of day: 65% of UVR reaches the earth between 10 am and 2 pm.

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Burns, Chemical
Burns, Thermal
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Dermatitis, Contact
Dermatitis, Exfoliative
Heat Exhaustion and Heatstroke
Systemic Lupus Erythematosus

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Lab Studies:

- None indicated for uncomplicated cases

Imaging Studies:

- None indicated for uncomplicated cases

Procedures:

- Skin biopsy may be useful if the diagnosis is in doubt or to exclude other diseases in the differential.

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Prehospital Care:

- In most cases, prehospital care involves providing simple first aid to treat patient symptoms.
- In severe cases, patients may develop second-degree burns, which rarely require aggressive fluid resuscitation and skin care.

Emergency Department Care:

- Most sunburns, while painful, are not life threatening, and treatment is primarily symptomatic.
- Aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) have antiprostaglandin effects and are useful to relieve pain and inflammation, especially when given early. Cool soaks with water or Burow solution also provide temporary relief.
- Systemic steroids may shorten the course and reduce the pain of sunburn when given early and in relatively high doses (equivalent to 40-60 mg/d of prednisone).
    - When used, prescribe them for only a few days, with no need for a taper.
    - In the presence of severe second-degree burns, steroids are best avoided because they increase the risk of infection.
    - Topical steroids show minimal, if any, benefit.
- Severe cases may require treatment of accompanying dehydration or secondary infection.
    - Severe cases may be associated with other heat-related illnesses, including heat exhaustion and heat stroke.
    - In rare cases, patients may require admission to a burn unit for aggressive skin care, intravenous fluids, and electrolyte management. Shock can occur.
- Prophylaxis of sunburn may be possible if a patient is treated with systemic steroids, equivalent to a daily dose of 60-80 mg of prednisone (1.0-1.5 mg/kg), prior to or shortly following sun exposure.

Consultations:

- Consult a dermatologist if the diagnosis of sunburn is in doubt or for children who appear to burn easily. In the latter case, a more serious underlying disorder may be present.
- Severe cases may require consultation with pediatricians or internists for hospital admission. Patients rarely require care in a dedicated burn unit.

Minor sunburn can be relieved to some extent with cool compresses or a cool bath. Administration of nonprescription analgesics and NSAIDs for the treatment of pain and inflammation is recommended.

Drug Category: *Analgesics* -- Pain control is essential to quality patient care. It ensures patient comfort and promotes pulmonary toilet. Most analgesics have sedating properties, which are beneficial for patients who have sustained sunburns.

Drug Name	Aspirin (Bayer, Anacin, Bufferin) -- Used for the treatment of mild to moderate pain. Also acts on the hypothalamus heat-regulating center to reduce fever.
Adult Dose	650 mg PO bid/tid/qid; not to exceed 4 g/d in equally divided doses
Pediatric Dose	10-15 mg/kg/dose q4-6h; not to exceed 60-80 mg/kg/d
Contraindications	Documented hypersensitivity; liver damage; hypoprothrombinemia; vitamin K deficiency; bleeding disorders; asthma; children (<16 y) with flu (because of association with Reye syndrome)
Interactions	Effects may decrease with antacids and urinary alkalinizers; corticosteroids decrease salicylate serum levels; additive hypoprothrombinemic effects and increased bleeding time may occur with coadministration of anticoagulants; may antagonize uricosuric effects of probenecid and increase toxicity of phenytoin and valproic acid; doses >2 g/d may potentiate glucose-lowering effect of sulfonylurea drugs
Pregnancy	D - Unsafe in pregnancy
Precautions	May cause transient decrease in renal function and aggravate chronic kidney disease; avoid use in patients with severe anemia, with history of blood coagulation defects, or taking anticoagulants

Drug Name	Ibuprofen (Advil, Motrin, Nuprin) -- Usually the DOC for the treatment of mild to moderate pain, if no contraindications are present.
Adult Dose	200-400 mg q4-6h while symptoms persist; not to exceed 3.2 g/d
Pediatric Dose	30-70 mg/kg/d tid/qid
Contraindications	Documented hypersensitivity; peptic ulcer disease; recent GI bleeding or perforation; renal insufficiency; high risk of bleeding
	Coadministration with aspirin increases risk of inducing serious NSAID-related adverse effects; probenecid may increase concentrations and, possibly, toxicity of NSAIDs;

Interactions	may decrease effect of hydralazine, captopril, and beta-blockers; may decrease diuretic effects of furosemide and thiazides; monitor PT closely (instruct patients to watch for signs of bleeding); may increase risk of methotrexate toxicity; phenytoin levels may be increased when administered concurrently
Pregnancy	B - Usually safe but benefits must outweigh the risks.
Precautions	Category D in third trimester of pregnancy; caution in congestive heart failure, hypertension, and decreased renal and hepatic function; caution in anticoagulation abnormalities or during anticoagulant therapy

Drug Name	Acetaminophen (Tylenol, Aspirin Free Anacin, Feverall) -- DOC for treatment of pain in patients with documented hypersensitivity to aspirin, upper GI disease, or oral anticoagulants.
Adult Dose	325-650 mg q4-6h or 1000 mg tid/qid; not to exceed 4 g/d
Pediatric Dose	<12 years: 10-15 mg/kg/dose q4-6h prn; not to exceed 2.6 g/d >12 years: 325-650 mg q4h; not to exceed 5 doses in 24 h
Contraindications	Documented hypersensitivity; G-6-PD deficiency
Interactions	Rifampin can reduce analgesic effects of acetaminophen; coadministration with barbiturates, carbamazepine, hydantoins, and isoniazid may increase hepatotoxicity
Pregnancy	B - Usually safe but benefits must outweigh the risks.
Precautions	Hepatotoxicity possible in chronic alcoholics following various dose levels; severe or recurrent pain or high or continued fever may indicate serious illness; acetaminophen is contained in many OTC products and combined use with these products may result in cumulative acetaminophen doses exceeding recommended maximum dose

Drug Category: *Corticosteroids* -- Have anti-inflammatory properties and cause profound and varied metabolic effects. Corticosteroids modify the body's immune response to diverse stimuli. May shorten the course and reduce the pain of sunburn.

Drug Name	Prednisone (Deltasone, Orasone, Meticorten) -- May decrease inflammation by reversing increased capillary permeability and suppressing PMN activity.
Adult Dose	40-60 mg/d PO
Pediatric Dose	1 mg/kg PO qd
Contraindications	Documented hypersensitivity; viral infection, peptic ulcer disease, hepatic dysfunction, connective tissue infections, and fungal or tubercular skin infections; GI disease
	Coadministration with estrogens may decrease prednisone clearance; concurrent use with digoxin may cause digitalis

Interactions	toxicity secondary to hypokalemia; phenobarbital, phenytoin, and rifampin may increase metabolism of glucocorticoids (consider increasing maintenance dose); monitor for hypokalemia with coadministration of diuretics
Pregnancy	B - Usually safe but benefits must outweigh the risks.
Precautions	Abrupt discontinuation of glucocorticoids may cause adrenal crisis; hyperglycemia, edema, osteonecrosis, myopathy, peptic ulcer disease, hypokalemia, osteoporosis, euphoria, psychosis, myasthenia gravis, growth suppression, and infections may occur with glucocorticoid use

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Further Inpatient Care:

- Inpatient care is indicated for severe burns, secondary infection, or control of severe pain.
- Indications for admission to a dedicated burn unit are the same as those for thermal burns.

Further Outpatient Care:

- Outpatient care is indicated for most cases of sunburn.
  - Cool baths or showers
  - Anti-inflammatory/analgesic medications
  - Avoidance of further sun exposure

In/Out Patient Meds:

- Topical anesthetic sprays or creams may cause sensitization and consequent dermatitis and, therefore, should be avoided.

Transfer:

- Only the most severe cases of sunburn, with marked involvement of a large percentage of the body surface area, require transfer to a burn unit for treatment.

Deterrence/Prevention:

- Prevention is the most effective therapy for sunburn. Individual and community educational programs can be effective in decreasing overall sun exposure or increasing use of sunscreen or protective clothing.

- Avoid sun exposure, especially during the period of peak solar radiation flux (from 10 am to 2 pm).
- Wear protective clothing, including hats or sun visors.
- Regularly use sunscreens with an adequate sun protection factor (SPF) for a given skin type (see Race).
    - SPF refers to the time needed to produce erythema on protected skin as a factor of the time to produce erythema on unprotected skin.
    - In general, use of a sunscreen with an SPF of 30 is sufficient.
    - Apply at least 30 minutes prior to sun exposure and reapply often.
    - Use waterproof sunscreens when swimming or perspiring heavily.
    - Physical barriers (eg, zinc oxide, talc, titanium dioxide) provide excellent protection but are less appealing cosmetically.
    - Chemical barriers are used in most sunscreens. Para-aminobenzoic acid (PABA) and PABA esters, which diffuse into stratum corneum and bind, are used most commonly, but they may stain clothing or produce contact dermatitis. Other chemical blocking agents include cinnamates, salicylates, anthranilates, and benzophenones. Many sunscreens employ a combination of agents.

Complications:

- Sunburns can exacerbate other skin diseases.
- Sunburns may trigger recurrence of herpes simplex, lupus, porphyria, or other cutaneous disorders.
- Sunburns may be associated with other heat-related illnesses, including dehydration, heat exhaustion, and heatstroke.
- Long-term exposure of the skin can lead to multiple deleterious effects, including premature aging and wrinkling of the skin (dermatoheliosis), development of premalignant lesions (solar keratoses), and development of malignant tumors (eg, basal cell carcinoma, squamous cell carcinoma, melanoma).
- Excessive exposure of the eyes to UVR can lead to discoloration of the lens and nuclear cataract formation.
- Photokeratoconjunctivitis, or snow blindness, may exist concurrently with sunburn.

Prognosis:

- Uncomplicated cases of sunburn resolve spontaneously over 4-7 days with scaling and

desquamation but without acute sequelae.

- Long-term exposure to UVR is associated with several deleterious effects on the skin, as delineated above.

Patient Education:

- Short- and long-term complications (see Complications)
- Prevention (see Deterrence/Prevention)
- For excellent patient education resources, visit eMedicine's Burns Center. Also, see eMedicine's patient education article Sunburn.

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Medical/Legal Pitfalls:

- Since window glass blocks UV-B, patients presenting with solar reactions occurring from exposure through window glass should be evaluated for phototoxic reactions and porphyria.
- Easy sunburning during infancy may indicate a serious underlying disease, such as porphyria or xeroderma pigmentosum. Referral for further evaluation is prudent.
- Obtain a complete drug exposure history in any patient with a rash.

Special Concerns:

- Avoid use of PABA and PABA esters on children younger than 6 months.

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Radiation Safety Answers

Answer to Question #13

Yale University has medical, veterinary, and research x-ray equipment. The specific types of x-ray equipment may be designed to image human patients, animals, viruses, ceramics, and for a large number of other purposes.

Yale has medical xray equipment used under the direction of a physician for diagnostic purposes. For example, the medical x-ray equipment located at the YHSC at 17 Hillhouse is surveyed and calibrated on a regular basis by physicists with the RSS. This equipment can only be operated by a trained person who is licensed with the State of CT Dept. of Environmental Protection.

All University owned x-ray equipment used for clinical reasons (ie. x-ray examinations on humans) is inspected by Radiation Safety to insure proper functioning. Shielding, personnel dosimetry requirements and safety procedures are handled by Radiation Safety. Only properly trained, certified personnel may expose humans using medical x-ray equipment.

Other x-ray equipment may include portables, C-arms, therapy units or diagnostic x-ray units. Use of such veterinary or cell irradiation x-ray equipment may also require shielding to protect persons in the surrounding area. Personnel dosimeters are generally required for personnel using veterinary x-ray equipment. Safe use of the equipment requires proper equipment use training. Safety procedures are supervised by Radiation Safety.

Radiation Safety should be notified as soon as any purchase of x-ray equipment is planned so that shielding and other safety requirements can be determined. X-ray equipment must be registered with the State of Connecticut Department of Environmental Protection. Any fees are the responsibility of the Principal Investigator.

For further information about State of Connecticut regulations and safe use of x-ray equipment, call Radiation Safety.

After appropriate training, persons at Yale may be permitted to use veterinary equipment for research projects that involve the x-raying of animals. These x-ray units are also surveyed for safety on a routine basis by members of the RSS.

X-ray diffraction units have very high dose rate x-ray beams. They can be used to image virus crystals and other materials. After appropriate, specific training, persons working at Yale may be allowed to use XRD units under the supervision of a Principal Investigator. [link to page 76 of manual]

The following information should be read by all users of x-ray diffraction units.

I. Hazards of Operating Machine Sources of X-Rays

The radiation from x-ray machines can be very dangerous, and such danger should not be minimized. On the other hand, there is no reason to be afraid to operate these machines after receiving proper training and instructions. The operator of an analytical x-ray machine should never become complacent or overconfident about the potential danger from an x-ray beam.

Numerous safety devices may be provided, but the user should not depend too heavily on these safety devices lest he become overconfident. If a safety device should fail unnoticed, serious injury may result. Adequate safeguards must be provided, but these can never replace constant vigilance and alertness to possible danger. Proper training in the operation of these machines should teach the nature of the hazards so that the user can be properly alert and vigilant.

The wavelengths of the x-rays used most commonly in x-ray diffraction and fluorescent x-ray spectroscopy fall in the range from approximately 0.5 to 10A. These are so-called "soft" x-rays which are readily absorbed in matter. A thickness of only a few mm or less of Al, Fe, or Pb is required to reduce the intensity of the transmitted beam to 1/10 that of the initial intensity even for x-rays with a wavelength of 0.5A. The 1.54A wavelength corresponds to CuKa radiation, and 1.93A is the wavelength of FeKa radiation. These are commonly used sources in x-ray diffraction work.

It is apparent that only relatively thin layers of shielding are required to protect against this radiation, but it is this same property that makes these x-rays very dangerous. They are highly absorbed in soft tissue, and severe burns can result from exposure of the hands, arms, skin or eyes to the direct or diffracted beams. The maximum permissible dose of radiation for various parts of the body are shown in Table I. For comparison, x-ray intensities that may be obtained with high-power tubes and strongly diffracting crystals are also shown in Table I. It is apparent that a dose of 100 to 500 times the permissible yearly dose may be obtained from a 1-second exposure to the most intense direct beam. Even a strong diffracted beam can deliver the maximum permissible yearly dose to the eye in less than 10 minutes.

II. Biological Effects of Intense X-Ray Beams

It is possible to provide a general classification of the kind of changes that ionization radiation can produce in skin. It is useful to categorize these effects into three areas.

1. Reversible changes.

2. Conditional reversible changes.

3. Irreversible changes

A. Reversible Changes

The most common and earliest reversible change is the production of reddening of the skin or erythema. If the dose and energy is low enough that most of the radiation is absorbed in the superficial layers of the skin, reddening occurs, then disappears apparently with no future effects. Another reversible change is the loss of hair or epilation. It is possible to give a dose of radiation that will stop cell division in the epithelial cells so that hair ceases to grow temporarily and falls out. With a low dosage, the hair will begin to grow after a period of time, with no apparent permanent ill effects. A third system that shows reversible effects are the sebaceous glands (oil-producing glands in the skin) which are temporarily affected to produce less sebum (oil secretion of these glands in the skin).

B. Conditional Reversible Changes

Pigmentation of the skin is not a totally reversible change. If a large area of skin is irradiated, erythema and pigmentation will occur with the pigmentation eventually fading. It has been shown that the resulting skin is not normal and has some "memory of the injury." Future doses of the same area do not produce the same skin response.

C. Irreversible Changes

If enough radiation of the proper energy is absorbed in the skin this will result in permanent destruction of either hair or sweat glands, or whole skin, with a resulting scar. The irreversible changes are categorized in the heading of:

1. Radiation Dermatitis

2. Chronic radiation dermatitis

3. Radiation cancer

A summary of the various effects to be expected after given acute dose to low energy x-rays and the time of exposure to receive the dose in the beam are given in Table II on page 75.

Sources of Exposure

1. The primary beam.

2. Leakage of primary beam through cracks in shielding.

3. Penetration of primary beam through shutters, cameras, beam stops, etc.

4. Secondary emission (fluorescence) from a sample or shielding material.

5. Diffracted rays from crystal.

6. Radiation generated by rectifiers in the high voltage power supply.

TABLE 1

NRC OCCUPATIONAL EXPOSURE LIMITS*

YEARLY LIMIT (mrem)

WHOLE BODY 5000

SKIN OF THE WHOLE BODY 50000

EXTREMITY 50000

LENS OF EYE 15000

MINORS (PERSONS UNDER THE AGE OF 18) 500

FETAL EXPOSURE 500/Nine months

*Note: State of Connecticut exposure limits vary slightly. For more information contact Radiation Safety.

If you would like more information, or have additional questions, please contact Aggie Barlow, Radiation Safety Officer.